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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,857	09/19/2003	Simon A. Burkitt	018781-010110US	5761

7590 03/17/2006

JONES DAY LLP
2882 SAND HILL ROAD
SUITE 240
MENLO PARK, CA 94025

EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/666,857	Applicant(s) BURKITT ET AL.	
	Examiner Rebecca L. Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 3,11-20,23,26,33,34 and 36-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5 and 8 is/are rejected.
- 7) ☒ Claim(s) 1,2,4-10,21,22,24,25,27-32 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

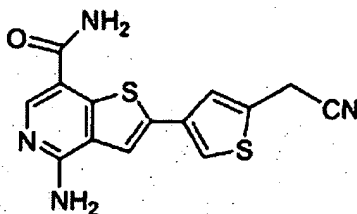
- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-45 are currently pending in the instant application. Claims 3, 11-20, 23, 26, 33, 34 and 36-45 are withdrawn from consideration as being for non-elected subject matter. Claims 1, 2, 4-10, 21, 22, 24, 25, 27-32 and 35 are objected and claims 1, 5 and 8 are rejected.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-32 and 35 and the further



election of the compound

in the reply filed on 22

December 2005 is acknowledged. The traversal is on the ground(s) that the restriction requirement should not be made final before applicants' review and *In re Weber*. This is not found persuasive because as stated on page 4 of the restriction requirement, the restriction requirement will not be made final until after applicant has been informed of the full scope of the elected invention. In regards to the *In re Weber* argument, this is considered non-persuasive because this decision involved rejections of claims under 35 U.S.C. 121 and not a restriction as is the case herein. The issue here is one of restriction. 35 U.S.C. 121 gives the Commissioner the authority to restrict to one invention those applications which contain two or more inventions, i.e. limit the examination of an application to a single invention. Thus, the requirement to restrict in this application is predicated on the fact that the elected subject matter taken as a whole

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and the non-elected subject matter taken as a whole are so different in structure and element as to be patentably distinct, i.e. a reference which anticipated but one group of compounds would not even render obvious the other group (two or more inventions involved). Applicants have not argued otherwise or presented any evidence to show that the various groups constitute the same invention, i.e. are obvious over each other. Applicants' traversal of the restriction requirement is based on its intra-claim restriction. Again, it is noted that the restriction requirement here is predicated on the premise that the various compounds involved (i.e. the elected and non-elected compounds) differ in structure and element so much so as to be patentably distinct, i.e., a reference which anticipated but the elected compounds claimed would not even render obvious the others. Accordingly, the requirement to restrict is considered proper.

Therefore, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination is:** The products of formula **Ia.1** wherein:

Y2 is $-\text{S}(\text{O})_m-$ wherein **m** is 0;

X1, X2 and X3 are independently selected from the group consisting of $=\text{C}-$ and $-\text{CH}-$;

Y1 and Y3 are independently $=\text{C}(\text{R5a})-$, $\text{C}(\text{R5})(\text{R6})$;

Z1 and Z2 are independently CH ;

Y4 is $=\text{N}=$ or $=\text{N}(\text{R5})-$;

R5a is independently selected from the group consisting of hydrogen, halogen, $(\text{C1-C6})\text{alkyl}$, $\text{cyclo}(\text{C3-C8})\text{alkyl}$, aryl , $\text{aryl}(\text{C1-C4})\text{alkyl}$, $\text{hetero}(\text{C1-C6})\text{alkyl}$, and $\text{arylhetero}(\text{C1-C4})\text{alkyl}$;

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R5 and **R6** are independently selected from the group consisting of hydrogen, (C1-C6)alkyl, cyclo(C3-C8)alkyl, aryl, aryl(C1-C4)alkyl, hetero(C1-C6)alkyl, and arylhetero(C1-C4)alkyl;

R1 is selected from the group consisting of $-C(O)NR1aR1b$, $-C(O)R1a$, $-CH(=NOH)$, $-N(R1b)C(O)R1a$, $-SO2NR1aR1b$, $-SO2R1a$, $-C(O)N(R1a)OR1b$, $-(C1-C4alkylene-N(R1b)C(O)R1a)$, $-(C1-C4alkylene-C(O)NR1aR1b)$; wherein **R1a** and **R1b** are selected from hydrogen, (C1-C6)alkyl, (C2-C4)alkenyl, (C3-C6)Heteroalkyl; hydroxyl(C1-C4)alkyl, fluoro(C1-C4)alkyl, cyano(C1-C4)alkyl, cyclo(C3-C8)alkyl, or mono-or di-hydroxycyclo(C3-C8)alkyl;

R2 is selected from the group consisting of $-NR2aR2b$ and $-OH$; wherein **R2a** and **R2b** are selected from hydrogen, (C1-C6)alkyl, (C2-C4)alkenyl, (C2-C6)heteroalkyl, mono-or di-hydroxy(C1-C4)alkyl, fluoro(C1-C4)alkyl, cyano(C1-C4)alkyl, cyclo(C3-C8)alkyl, mono-or di-hydroxycyclo(C3-C8)alkyl, aryl, aryl(C1-C4)alkyl, $-C(O)-(C1-C4)alkyl$, $-C(O)-(C1-C4)alkoxy$ or $C(O)-fluoro(C1-C4)alkyl$;

L is a single bond; and

Q is selected from the group consisting of furyl, thienyl, thiazolyl, isothiazolyl, triazolyl, imidazolyl, oxazolyl, isoxazolyl, pyrrolyl, pyrazolyl, benzofuryl, tetrahydrobenzofuryl, isobenzofuryl, benzthiazolyl, benzoisothiazolyl, benzotriazolyl, indolyl, isoindolyl, benzoxazolyl, benzimidazolyl, benisoxazolyl and benzothieryl.

The remaining subject matter of claims 1, 2, 4-10, 21, 22, 24, 25, 27-32 and 35 that is not drawn to the above elected invention and the subject matter of claims 3, 11-20, 23, 26, 33, 34 and 36-45 stands withdrawn under 37 CFR 1.142(b) as being for non-

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elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds of the formula (I) wherein W is a 5-5 or 6-6 bicyclic ring system or a 5-6 bicyclic ring system (other than that as found in Ia.1); wherein X1, X2 and X3 are -N-; Y1 and Y3 are =N-, -N(R5)-, -O- and -S(O)m-; Y2 is =C(R5a)-, -C(R5)(R6), -C(O)-, =N-, =N(R5)-, -O-; Y4 is =C(R5a)-, -C(R5)(R6), -C(O)-, -O- and -S(O)m; Z1 and Z2 are N; R1 is heteroaryl, heterocyclo(C3-C8)alkyl, heterocyclo(C3-C8)alkyl-(C1-C4)alkyl; R1a is attached to an adjacent ring member of W relative to the point of attachment of R1 to form an additional 5- or 6-membered fused ring, or R1a and R1b are combined with their intervening atoms to form a 3-, 4-, 5- or 6-membered ring; R2 is heterocyclo(C3-C8)alkyl, heterocyclo(C3-C8)alkyl-(C1-C4)alkyl, heteroaryl, heteroaryl(C1-C4)alkyl, -C(O)-heterocyclo(C3-C8)alkyl; R2a and R2b may be combined with the nitrogen atom to which each is attached to form a 5-, 6-, or 7-membered ring containing from 1-3 heteroatoms selected from N, O and S; L is (C1-C4)alkylene, -C(O)-, -C(O)NR3-SO2N(R3), -C(R3)=C(R4)-, -O-, -S- and -N(R3)-; Q is selected from the group consisting of (C2-C6)alkenyl, (C2-C6)alkynyl, halogen, aryl, phenyl, naphthyl, pyridyl, pyrrolidinyl, pyrazinyl, pyridazinyl, pyrimidyl, quinolyl, tetrahydroquinolyl, isoquinolyl, cyclopentyl and cyclohexyl, etc.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and

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composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as by pyridyl, pyrrolidinyl, quinolyl, isoquinolyl, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 546 subclass (268.1)+ pyridyl, class 548 subclass (579)+ pyrrolidinyl, class 546 subclass (152)+ quinolyl, class 546 subclass 139(+) isoquinolyl, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Claim Objections

Claims 1, 2, 4-10, 21, 22, 24, 25, 27-32 and 35 are objected to as containing non-elected subject matter. Claims 1, 2, 4-10, 21, 22, 24, 25, 27-32 and 35 presented drawn solely to the elected invention identified supra as, **the elected invention for search and examination**, would overcome this objection.

Claims 1, 2, 4-10 and 35 are objected to as being dependent upon a rejected base claim, but would appear allowable over the prior art of record if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims and presented drawn solely to the elected invention for search and examination as identified supra.

Non-Elected Subject Matter Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The non-elected subject matter of Claims 1, 5 and 8 is rejected under 35 U.S.C. 102(b) as being anticipated by FRALEY et al. (WO 01/28993). The rejection of the non-elected subject matter of claims 1, 5 and 8 is made in support of the restriction requirement presented supra.

FRALEY et al. discloses the compound of registry #335672-39-4, 7-chloro-1,2-dihydro-2-oxo-3-quinolinecarboxamide which corresponds to applicants' non-elected subject matter of claims 1, 5 and 8 wherein Q is halogen; L is a single bond, W is quinoline; R1 is C(O)NR1aR1b and R2 is -OH. Specifically, the compound 7-chloro-1,2-dihydro-2-oxo-3-quinolinecarboxamide is a tautomer of applicants' instant non-elected subject matter of claims 1, 5 and 8. Page 21 of FRALEY et al. discloses that the compound A is understood to include tautomeric structure B, and vice versa. This reference anticipates the non-elected subject matter of applicants' instant claims since it discloses tautomers of applicants' non-elected subject matter and tautomers rapidly interconvert between the two substances and exist in a state of equilibrium between the two isomeric forms. FRALEY et al. also discloses the tautomers of compounds 7-3 (page 67) and 9-3 (page 72) which correspond to applicants' non-elected subject matter of claim 1 wherein Q is halogen, L is a single bond; W is quinoline; R1 is heteroaryl, (i.e.

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benzimidazole); and R2 is OH. FRALEY et al. also discloses the tautomer of compound 13-2 (page 80) which corresponds to applicants' non-elected subject matter of claim 1 wherein Q is (C1-6)alkoxy; L is a single bond; W is quinoline; R1 is heteroaryl (i.e. benzimidazole); and R2 is OH.

Conclusion

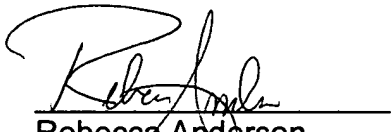
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Rebecca Anderson', is written over a horizontal line.

Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

March 8, 2006